Confédération des industries agro-alimentaires de l'UE
Confederation of the food and drink industries of the EU

TCO/087/03E-B-Final

Brussels, 3rd April 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061.
Rockville, MD 20852
USA

RE: CIAA comments - US Bioterrorism Act - Section 307
Docket No. 02N-0278 (Prior notice)

Dear Sir or Madam,

The Confederation of the EU Food and Drink Industries (CIAA) welcomes the opportunity to provide comments on the FDA proposals to implement Sections 307 of the Bioterrorism Act.

CIAA represents the largest manufacturing industry in the EU with 600 billion euros production value. CIAA members are also major employers since 2.6 million employees work in the sector in the EU, equivalent to 12% of the total employment in the manufacturing sector.

In principle, CIAA considers legitimate the US objective to protect consumers against the risk of intentional adulteration or any other sort of risks concerning products that are marketed to US consumers.

However, CIAA is very concerned about the disproportionate character of the law. Despite the constraining and detailed provisions that will have to be respected by imported goods, the law will be ineffective in eliminating the risk of contamination or adulteration. CIAA considers that the measures envisaged to be applied to food imports will impose heavy and costly burdens upon EU exporters and will act as a clear non tariff barrier. Small and medium sized companies in particular risk being

Avenue des Arts, 43 • B-1040 Bruxelles
Tel.: +32 2 514 11 11 • Fax: +32 2 511 29 05 • E-mail: ciaa@ciaa.be • Web: http://www.ciaa.be

prevented from continuing to export to the US as the new regulations and the administrative burdens imposed on them render their exports too costly to be economically viable.

The FDA proposals are also in clear contradiction with attempts made within WTO in the context of current negotiations to agree on measures that would facilitate trade through the simplification and streamlining of customs procedures.

You will find enclosed further more specific and detailed comments on certain provisions of the proposed laws which should be simplified or amended in order to relieve some of the burden that EU exporters and US importers will have to bear. CIAA would therefore be grateful if the FDA would give consideration to how it may effectively resolve the issues which are raised in this submission without undermining the objective of its legislation.

Yours sincerely,

R. Destin
Director General

Enclosure

Specific CIAA comments to the FDA proposals on Prior Notification

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The importer or the purchaser will have to provide for prior notice due by noon of the calendar day before the article of food arrives at the port of entry. This provision will impose heavy administrative burdens on operators as a prior notification will have to be submitted for each different product in a shipment, and for each different format / packaging of the same product.

- Generally, the FDA asks for too much and too detailed information. Some data required in the proposed prior notice system do not produce a major benefit in terms of reducing risk related to food imports while, at the same time, they impose important burdens on food companies.

- In particular, unduly detailed information is requested by the FDA when requiring the precise quantity by package size of all shipped goods. In order to make a decision about whether to inspect a shipment, it must suffice to know the overall quantity of goods offered for importation. The FDA requirement regarding lot or production codes will also unduly complicate the prior notice. The FDA should not require this information as it is of no value in deciding whether to inspect an article of food.

- For practical reasons, it is impossible to include the FDA registration numbers for all operators that have handled the imported food in the prior notice. In addition, it is difficult to see why this information should be useful to FDA for all shipments. In case of a risk related to food imports the requirement to keep records of suppliers / customers („one up - one down“) should be enough to help FDA take appropriate steps.

- Concerning the grower's identity, CIAA would like to have assurances that the submission of information on the grower is required only if that information is known and that, in the case of processed foods, these would be exempted because growers are mostly unknown.

- Taken together, the simplications on prior notice information requirements proposed above would enormously ease the burden for exporters. As long as prior notice requires the operator to actively submit information to the FDA rather than relying on US Customs to forward the customs declaration to the FDA automatically, the information requirements must be as simple and easy as possible.

- Having said this, we would like to stress again, that US Customs already receive notice of the arrival of each ship and its manifest well in advance of the ship´s arrival. Most of the data required for the prior notice are provided to Customs. There should be no need for the FDA to require duplicate information already obtained by Customs. A close coordination between the FDA and US Customs Service is necessary to avoid unnecessary and redundant regulations. Duplicative regulations are costly for both the industry and the administration.

- Indeed, during an outreach meeting in Brussels, FDA officials mentioned that, when the requirement goes into effect, the existing data collection system of the US Customs Service (ACS) will not be used because it cannot be modified to accommodate the additional data requirements of the prior notice system prior to the December 12, 2003,

statutory deadline. In this connection, we understand that US Customs is in the process of developing a new system as a replacement for the ACS. However, implementation is not expected until 2005 which is too late.

- By requiring notice by noon of the day before the anticipated imports, the number of updates will be increased; Indeed, an update is required if the anticipated time of arrival is more than one hour earlier or three hours later than expected. Several unexpected situations could lead to such a delay. If the update is not filed or is wrongly filed, the sanction regime will apply. That is the reason why CIAA requests more flexibility in terms of the time of arrival at ports of entry, where the actual time differs from the antitcipated written on the initial prior notice.

- Regarding the sanctions regime under the proposed rule, the purchaser, owner, importer, or consignee would be responsible for the correct implementation of the rule. Nevertheless, in the end, it is the exporter who will bear the economic consequences of a detention of the products. Moreover, it would be unfair to sanction an exporters even though the same data are available in another agency, namely Customs.

- In order to get the system operational step-by-step and not disrupt trade flows a period of exemption from prosecution should be foreseen for operators who supply inadequate or incomplete information.

- CIAA is concerned about the treatment of samples under the Prior notice regulations. Clarification is requested on whether shipments of small quantities for market-testing or tasting will be permitted without being subject to Prior notice requirements.

Finally, further to the rule-making on the Bioterrorism Act, CIAA is concerned about the other new US rules relating to international trade which were also inspired by the aim to increase security and prevent terrorist attacks - namely the Container Security Initiative (CSI) and the Customs-Trade Partnership Against Terrorism (C-TPAT). It is CIAA´s suggestion, therefore, to create links between the different projects in that compliance with one automatically counts as compliance with others. For example, shipments originating in a CSI harbour could be exempt from the prior notice at the FDA. Or, companies taking part in the C-TPAT could be exempt from the proposed keeping of records and from having to register explicitly with the FDA (this could be done internally between US agencies).